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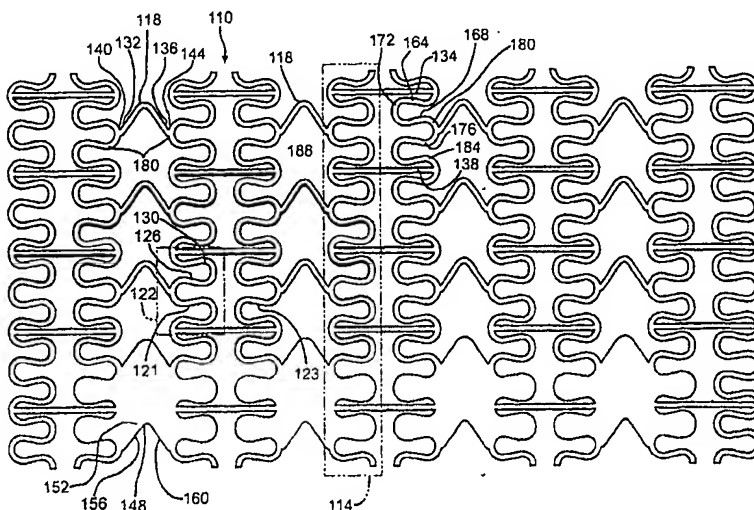
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(54) Title: **PARTIALLY BIODEGRADABLE STENT**



(57) Abstract: A stent is provided which after expansion within the body remains substantially rigid for a certain time, at which point the stent becomes increasingly conformable, due to the biodegradation of the connecting members (118), and thereby avoids mechanical irritation to the body's tissue. Other portions of the stent structure may also biodegrade during this time. Also provided is a method of expanding such a stent.

PARTIALLY BIODEGRADABLE STENT

BACKGROUND

[0001] This invention relates to a partially biodegradable radially expandable stent.

[0002] Surgical stents have long been known which can be surgically implanted into a body lumen, such as an artery, to reinforce, support, repair or otherwise enhance the performance of the lumen. For instance, in Interventional Cardiology it is often desirable to place a stent in the coronary artery at a location where the artery is narrowed or is susceptible to closure. The stent, once in place, reinforces that portion of the artery allowing normal blood flow to occur through the artery. One form of stent which is particularly desirable for implantation in arteries and other body lumens is a cylindrical stent which can be radially expanded from a first smaller diameter to a second larger diameter. Such radially expandable stents can be inserted into the artery by being located on a balloon and fed internally through a guiding catheter placed in the vasculature of the patient until the unexpanded stent is located where desired. The balloon or other expansion mechanism is then inflated which exerts a radial pressure outward on the stent causing the stent to expand radially to a larger diameter. Still other stents are self-expanding. Regardless of the expansion method, expandable stents exhibit sufficient rigidity after being expanded that they will remain expanded after the catheter has been removed.

[0003] Radially expandable stents come in a variety of different configurations to provide optimal performance in various different particular circumstances. For instance, the patents to Lau (U.S. Pat. Nos. 5,514,154, 5,421,955, and 5,242,399), Baracci (U.S. Pat. No. 5,531,741), Gaterud (U.S. Pat. No. 5,522,882), Gianturco (U.S. Pat. Nos. 5,507,771 and 5,314,444), Termin (U.S. Pat. No. 5,496,277), Lane (U.S. Pat. No. 5,494,029), Maeda (U.S. Pat. No. 5,507,767), Marin (U.S. Pat. No. 5,443,477), Khosravi (U.S. Pat. No. 5,441,515), Jessen (U.S. Pat. No. 5,425,739), Hickie (U.S. Pat. No. 5,139,480), Schatz (U.S. Pat. No. 5,195,984), Fordenbacher (U.S. Pat. No.

5,549,662) and Wiktor (U.S. Pat. No. 5,133,732), each include some form of radially expandable stent for implantation into a body lumen.

[0004] As the above listed patents demonstrate, a wide variety of stents are known in the prior art. Typically, stents are tube-shaped and flexible in their pre-expanded configuration. Stents often comprise a plurality of cylindrical, serpentine rings joined by connecting members. The connecting members for many of the prior art stents are flexible before the stent is expanded. When a stent is implanted (i.e., expanded) into a vessel, good scaffolding is desired initially to support the tissue and keep the vessel patent. Many of the prior art stents adequately support the tissue upon their deployment, and quite often, the connecting members become relatively rigid after expansion. However, because the connecting members are often relatively rigid after deployment, many of the prior art stents experience a problem with causing mechanical irritation to the tissue due to their lack of flexibility.

[0005] What is needed is a stent which will remain relatively rigid for a certain amount of time after expansion within the vessel in order to provide structural support until the body endothelializes the stent, and which will then become more conformable to avoid mechanical irritation to the body's tissue. The present invention satisfies these and other needs.

SUMMARY

[0006] It is an object of the invention to provide an expandable stent which after expansion with the body will become substantially rigid for a given time, and will then become increasingly flexible to avoid irritation to the body's tissue.

[0007] In one aspect, an expandable stent comprises a plurality of substantially cylindrical, serpentine ring structures. Each ring structure extends around a circumference of the stent and comprises at least one unit structure. The unit structure comprises a plurality of strut members and a plurality of bends which form a substantially zig-zag pattern. When the stent is in an unexpanded state, at least one connector member joins two of the

ring structures. The connector member is biodegradable and adapted to biodegrade when the stent is in an expanded state so that the two ring structures become substantially disjoined.

[0008] In another aspect, a method of expanding a stent comprises providing an expandable stent. In an unexpanded state, the stent comprises a plurality of substantially cylindrical, serpentine ring structures. Each ring structure extends around a circumference of the stent, and at least one biodegradable connector member joins two of the ring structures. The stent is delivered in an unexpanded state to a desired deployment site within a mammalian body, where the stent is expanded. Finally, the connector member is biodegraded so that the two ring structures become substantially disjoined.

[0009] The expandable stent of the invention allows the stent to be expanded within the body and remain substantially rigid for a certain time, at which point the stent becomes increasingly conformable, due to the biodegradation of the connecting members, and thereby avoids mechanical irritation to the body's tissue.

[0010] The present invention, together with further objects and advantages, will be best understood by reference to the following detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWINGS

[0011] Figure 1 is a partial view of a prior art Zilver-stent in a pre-deployment configuration.

[0012] Figure 2 is a partial view of the stent of Figure 1 in a deployed configuration.

[0013] Figure 3 is a partial view of a V-flex stent having biodegradable connecting members in an expanded configuration prior to degradation of the connecting members.

[0014] Figure 4 is a partial view of the V-flex stent of Figure 3 in an expanded configuration after degradation of the connecting members.

[0015] Figure 5 is a partial view of a Z-stent having biodegradable connecting members.

[0016] Figure 6 is a cut open and unfolded view of a segment of interconnected spring members in a Z-stent device having biodegradable connecting members.

[0017] Figure 7 is an enlarged segment showing a biodegradable connecting member fastened to an arm section in a spring member of a Z-stent device.

[0018] Figure 8 is a view of one half of a Z-stent device shown without graft material.

[0019] Figures 9-11 are enlarged views of a biodegradable connecting member and spring members in a Z-stent device in an unloaded state, at an axial pressure load, and at an axial tensile load, respectively.

[0020] Figure 12 is a partial view of the Z-stent of Figure 6 in an expanded configuration after degradation of the connecting members.

[0021] Figure 13 is a partial view of an abdominal aorta aneurysm (AAA) device having biodegradable connecting members.

[0022] Figure 14 is a partial view of the AAA device of Figure 13 in an expanded configuration after degradation of the connecting members.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0023] The following description of preferred embodiments of the invention provides examples of the present invention. The embodiments discussed herein are merely exemplary in nature, and are not intended to limit the scope of the invention in any manner. Rather, the description of these preferred embodiments serves to enable a person of ordinary skill in the art to make and use the present invention.

[0024] As shown in the drawings for purposes of illustration, the present invention is directed to a partially biodegradable stent. The invention is applicable to stents having different types of configurations as known in the art, such as a V-flex stent, a Zilver-stent, a Z-stent, and a Y-shaped (or AAA "abdominal aorta aneurysm" device) stent, and is applicable to different deployment systems known in the art, such as self-expanding or balloon expandable systems.

[0025] Fig. 1 shows a prior art Zilver-stent 10 mounted on a catheter device 34 in a pre-deployment (unexpanded) configuration. Before insertion into a patient's body, the stent 10 is placed over the expandable balloon 20 and crimped (collapsed, restrained) onto the balloon in order to form a reduced profile for insertion into the body through small diameter, tortuous-pathed arteries or other vessels or lumens within the body. In other prior art systems, a self-expanding stent may be utilized. Typically, the catheter device 34 is advanced through a patient's body in its unexpanded state by deploying a small guide wire (not shown) and advancing the catheter device over the guide wire to its final destination such as a partially blocked artery 38. The balloon 20 is then inflated by methods known in the art to expand the stent radially so that the stent 10 abuts against the walls of the artery 38 as shown in Fig. 2.

[0026] As seen in Fig. 2, the prior art stent 10 utilizes a plurality of ring structures 14 interconnected by a plurality of generally straight connector members 18. In other prior art, the connector members 18 may have flexible, curved portions, such as U, V, or W shaped portions, and the ring structures

may be in varying configurations. Each ring structure 14 comprises a repeating pattern of unit structures 22. The unit structures 22 are made up of a repeated pattern of a plurality of struts 26 joined together by bends or apexes 30.

[0027] After deployment, the balloon 20 is deflated, and the catheter device is removed from the patient's body. The stent 10 remains in the expanded configuration in the artery to hold the artery open and prevent further blockage. In much of the prior art, the connector members 18, along with the stents themselves, remain relatively rigid after the stent is expanded in order to support the walls of the artery. Unfortunately, the lack of flexibility of these prior art stents after expansion often eventually leads to mechanical irritation of the tissue surrounding the stent.

[0028] The present invention solves this problem by providing a stent that, after expansion within a mammalian body, remains substantially rigid for a certain time, at which point the stent becomes increasingly conformable and thereby avoids mechanical irritation to the body's tissue. In order to accomplish this, the invention generally provides for biodegradable connector members which are substantially intact when the stent is in its unexpanded form, which remains substantially intact for some time after the stent is expanded within the body, and which after a given time substantially biodegrade. The remainder of the stent preferably retains its composition after expansion. In other embodiments, the remainder of the stent may contain biodegradable portions which also substantially biodegrade after a given time.

[0029] Preferably, the biodegradable connector members are made of one or more biodegradable polymers in varying combinations, such as polymers, copolymers, and block polymers. Some examples of such biodegradable (also bio-resorbable) polymers include poly-lactic acid, polyglycolic acid, polyglycolides, polylactides, polycaprolactones, polyglycerol sebacate, polycarbonates e.g. tyrosine derived, polyethylene oxide, polybutylene terephthalate, polydioxanones, hybrids, composites, collagen matrices with growth modulators, proteoglycans, glycosaminoglycans,

vacuum formed SIS (small intestinal submucosa), fibers, chitin, and dextran. Any of these biodegradable polymers may be used alone or in combination with these or other biodegradable polymers in varying compositions. The biodegradable connector members 18 may comprise a variety of shapes including, amongst others, a U shape, a V shape, a W shape, a generally curved shape, or may be substantially straight. The rest of the stent structure including the ring structures, is preferably made of one or more medically acceptable, i.e., biocompatible, materials which provide the desired longitudinal flexibility and radial strength. Some examples of suitable materials include shape memory alloys such as nitinol, stainless steel, 316 L stainless steel, cobalt chromium, nickel titanium, platinum, inconel, or any other material known in the art. As will be shown in differing embodiments below, the plurality of ring structures preferably form a substantially serpentine, cylindrical, and generally zig-zag shape extending around the circumference of the stent. Similarly, the unit structure preferably comprises a plurality of strut members and bends in a substantially zig-zag pattern. In other embodiments, the ring and unit structures may comprise other configurations, including a more linear, non-cylindrical configuration.

[0030] Preferably, for the embodiments discussed below, prior to expansion the stent forms a substantially flexible, integral, one-piece tubular shape having substantially flexible, biodegradable connector members. In other embodiments, the stent may comprise a variety of configurations such as a multiple piece tube or may have a non-tubular shape. After expansion and prior to the connector members biodegrading, the stent preferably becomes a relatively rigid, one-piece tube in order to provide the vessel or artery with good structural support until the body endothelializes the stent. In other embodiments, the stent may retain a non-tubular shape or multiple piece tubular shape. The biodegradable connector members are preferably substantially more rigid at this point relative to their pre-expanded state.

[0031] Preferably, for the embodiments discussed below, within the range of thirty (30) days to one-hundred-eighty (180) days after the stent has been expanded within the body, the connector members substantially biodegrade to

leave a stent with substantially unconnected ring structures. However, longer or shorter degradation periods are also contemplated. The degradation rate is based in large part on what materials are utilized for the biodegradable connector members, in addition to the thickness of the connector members. In some embodiments, the biodegradable connector members may comprise multiple layers of varying biodegradable polymers, each with differing degradation rates. Some layers may biodegrade quickly and other layers may undergo prolonged degradation. In other embodiments, the biodegradable connector members may comprise a single layer of a biodegradable polymer or a composite layer made up of a combination of varying biodegradable polymers. In these embodiments, the single layer may degrade at a substantially uniform rate.

[0032] In some embodiments, the ring structures may become completely disconnected. The structure of the remainder of the stent preferably retains its composition. At this point in time, the stent preferably becomes a modular, segmented stent comprising multiple disconnected tubular portions which allows the stent to become flexible and conformable so as to substantially avoid mechanical irritation to the body's tissue. In other embodiments, the stent may retain a non-tubular shape, or a substantially integral tubular shape.

[0033] In other embodiments, some of the remaining structure of the stent may also biodegrade. For instance, the ring structures may comprise a non-biodegradable base material, such as stainless steel, and the base material may be coated with one or more layers of biodegradable polymers in varying combinations and degradation rates. In these embodiments, within a given time after the stent is expanded (preferably within 30 to 180 days), the one or more layers of biodegradable polymers will biodegrade leaving only the non-biodegradable base material. At this time, the cross-section of the ring structures will be diminished leaving a more flexible stent structure. In other embodiments, the base structure may comprise a mixture of non-biodegradable materials and biodegradable polymers, with the biodegradable polymers biodegrading after a given time to leave only the non-biodegradable materials thereby allowing for more flexibility of the stent structure. In any of

these embodiments, one or more drugs may be incorporated into one or more layers of the ring structures, such as anti-restenosis drugs, anti-inflammatory drugs, anti-thrombotic drugs, and growth factor or growth modulating drugs thereby inhibiting or accelerating tissue formation. These drugs may be mixed directly into one or more layers of the ring structures or may be enclosed within a cavity of the ring structures themselves for dispersion after biodegradation begins.

[0034] Figures 3-14 depict the invention. Fig. 3 illustrates a stent 110 in an expanded configuration shortly after deployment and prior to the biodegradable connector members degrading according to a preferred embodiment of the invention in which the substantially biodegradable connector members are utilized in a V-flex stent. Some representative examples of V-flex stents known in the art are disclosed in US patent number 5,843,175 and 5,868,782 to Global Therapeutics, Inc. and US patent number 6,042,606 to Cook, Inc. which are hereby incorporated by reference. In the preferred embodiment, the stent 110 comprises a plurality of serpentine (zig-zag or undulating) ring structures 114 interconnected by a plurality of biodegradable connector members 118. Each ring structure 114 is a substantially circular ring comprising an endless pattern of unit structures 122. The unit structure 122 represents a specific configuration of the wire members, including the struts 126 and bends 130, that comprise the structural component of the stent 110.

[0035] Preferably, as illustrated in Fig. 3, some adjacent unit structures 122 are connected together by first and second tie-bars 134 and 138. The repeated unit structure 122 of each ring structure 114 preferably comprises first and second struts 164 and 168 joined together by a first bend 172, a third strut 176 joined to the second strut 168 by a second bend 180, and a fourth strut 184 joined with the third strut 176 by a third bend 188. In other embodiments, the unit structure may be modified to include a varying number of struts and bends in differing configurations. The ring structures 114 depend on the configuration of the unit structures 122 and as a result may also comprise a variety of configurations in varying embodiments.

[0036] The struts and bends of the unit structure 122 preferably form repeated U or V shapes, but in other embodiments may be in varying configurations. The U or V shapes provide many advantages, such as being easily repeated around the circumference of the ring structures 114. Additionally, the U or V shapes facilitate the staggered arrangement of bends. Another advantage of using the U or V shapes is the availability of central attachment points for connecting members, as is more fully described below.

[0037] The ring structures 114 are interconnected to form the stent 110 by a plurality of biodegradable connector members 118. As illustrated in Fig. 3, each biodegradable connector member 118 joins first and second ring structures 114 and is preferably disposed between two adjacent unit structures 122. In other embodiments, each biodegradable connector member 118 may be disposed between adjacent unit structures in varying configurations, such as between W or Z shaped configurations.

[0038] Each biodegradable connector member 118 has a first end 132 and a second end 136. The first end 132 of each biodegradable connector member 118 is joined to a peak 140 of the second bend 180 of each unit structure 122 on the first ring structure 114. The second end 136 of each biodegradable connector member 118 is joined to a peak 144 of the second bend 180 of each adjacent unit structure 122 on the second ring structure 114. In other embodiments, varying configurations may be used to join the adjacent unit structures 122 of the ring structures 114 with the biodegradable connector members 118. For example, the biodegradable connector members 118 may join adjacent first bends 172 of adjacent unit structures 122 on separate ring structures 114, or may join adjacent third bends 188 of adjacent unit structures 122 on separate ring structures 114. As illustrated in Fig. 3, it is preferable that each unit structure 122 of each ring structure 114 is connected to two biodegradable connector members 118. In other embodiments, a varying number of biodegradable connector members 118 may be used to join each ring structure 114.

[0039] In addition to the first and second ends 132 and 136, each biodegradable connector member 118 also includes an undulating portion

148. The undulating portion 148 provides longitudinal flexibility to the stent 110. A variety of configurations can be used for the undulating portion 148, such as U, V, W, or Z shapes. The biodegradable connector segments 118 shown in Fig. 3 illustrate a preferred configuration for the undulating portions 148. In this preferred embodiment, each undulating portion 148 comprises an inverted "V" shape 152 made up of first and second legs 156 and 160. This configuration simplifies manufacture while providing the desired undulating portion 148 that confers axial flexibility onto the stent 110.

[0040] As illustrated in Fig. 3, it is preferable that the undulating portion 148 be positioned in the space 162 between each ring structure 114 without being overlapped by any of the tie-bars 134 and 138, struts 164, 168, 176, and 184, or bends 172, 180, and 188 of the adjacent unit structures 122. This allows the maximum possible flexibility of the undulating portion 148 by avoiding any potential abutment against the undulating portion 148. This configuration provides the desired axial flexibility while maintaining radial strength of the stent 110. Also, this configuration facilitates manufacturing due to the use of aligned portions. In other embodiments the undulating portion 148 may overlap the above-referenced members.

[0041] As depicted in Fig. 3, adjacent ring structures 114 are preferably radially aligned with each other. That is, adjacent ring structures 114 are preferably aligned such that axially adjacent unit structures 122 lie in complementary position relative to each other. Particularly preferable, all ring structures 114 of the stent 110 are radially aligned in this manner. However, other configurations may be used including staggered adjacent ring structures 114. As shown, it is preferable that the biodegradable connector members 118 joining adjacent ring structures 114 are in circumferential alignment relative to one another. This preferred arrangement arises due to the uniformity of the "V" shaped biodegradable connecting members 118 and unit structures 122, all arranged in alignment with one another. This arrangement maintains the desired axial flexibility while also contributing to the radial strength of the stent 110 and facilitating manufacturing. In other

embodiments, the biodegradable connector members 118 joining adjacent ring structures 114 may be circumferentially displaced relative to one another.

[0042] Fig. 4 illustrates the stent 110 of Fig. 3 in an expanded configuration within the range of thirty (30) to one-hundred-eighty (180) days after the stent 110 has been expanded within the body and the connector members 118 have substantially biodegraded to leave the stent 110 with a plurality of substantially unconnected ring structures 114. As shown, the structure of the remainder of the stent 110 preferably retains its composition although, as discussed previously, the remainder of the stent may also biodegrade. At this point in time, the stent 110 is a modular, segmented stent 110 comprising multiple disconnected ring structures 114 which are preferably generally tubular and which allow the stent 110 to become flexible and conformable so as to substantially avoid mechanical irritation to the body's tissue. In other embodiments, the stent may retain a non-tubular shape, or a substantially integral tubular shape.

[0043] Fig. 5 illustrates a stent 210 in an expanded configuration shortly after deployment and prior to the biodegradable connector members 218 degrading according to a preferred embodiment of the invention in which the substantially biodegradable connector members 218 are utilized in a Z-stent. Some representative examples of Z-stents known in the art are disclosed in Australian patent number 729883 to William Cook Europe A/S which is hereby incorporated by reference.

[0044] As shown in Fig. 5, a Z-stent device 210 may be formed as a single tube, but a stent may also in other embodiments comprise a branched structure such as a Y-shaped structure with a relatively large tube branching into two smaller tubes. The stent device as a single tube can be used for treatment of a single-lumen vessel, such as to recreate the lumen of the vessel at a stenosis, for use as a vessel prosthesis at an aneurysm or a fistula, or at some other vessel anomaly. Under the invention, the stent device 210 comprises a graft 200 supported by tubular members 205, which are constructed from a plurality of cylindrical spring members 216

interconnected by biodegradable connecting members 218. A Z-stent device with a Y-shaped structure may be used to treat an abdominal aorta aneurysm.

[0045] The individual spring members 216 are Z-stents of a well-known design made of a wire of stainless steel, nitinol, a resilient plastics material, or a metallic material or composite which can exhibit elastic or superelastic properties. The wire is formed in a zig-zag configuration extending through a cylindrical surface, and the wire ends are joined together to make it endless, so that the cylindrical spring member is closed. Fig. 6 shows three spring members which are cut open along the line a and unfolded to a planar shape for the sake of clarity. The longitudinal direction of the tubular member is indicated by the arrow b. It should be noted that the different figures use the same reference numerals for details of the same type.

[0046] A spring member 216 includes a plurality of arm sections 222, each extending between two elbow sections 226. The arm sections are shown as approximately straight in their unloaded state, which is preferred to obtain high axial rigidity, but they may also be curved. The elbow sections are shown as simple bends in which the wire extends in a simple angle of a suitable radius of curvature. However, the elbow sections may have a more complex design in which the wire at the end of the arm section is formed, for example, as shown in Fig. 5 in EP-A1 0539237.

[0047] As shown in Fig. 6, the biodegradable connecting members 218 may extend obliquely in relation to the longitudinal direction b of the stent device 210. In the stent's expanded and unexpanded states, the biodegradable connecting members 218 are seen to extend largely in parallel with the arm sections 222 and also mutually in parallel. The stent's ring structure is depicted by 214 and the stent's unit structure is depicted by 220. The embodiment shown in Fig. 6 is one preferred stent arrangement, although other arrangements may also be utilized. As shown in Fig. 6, a gap g follows a pair of interconnected arm sections, followed by another pair of interconnected arm sections. In the gap, the elbow sections are free to move closer to or further away from each other.

[0048] Fig. 8 shows an expanded view of the arrangement of Fig. 6. In the case of the advantageous locations of the biodegradable connecting members 218 shown in Fig. 8, between each of the arm sections having a mounted biodegradable connecting member 218 there is an arm section without any biodegradable connecting member. Thus both in the circumferential direction and in the longitudinal direction there is a free elbow section. With this open structure, the individual spring members can be resiliently deformed as indicated in Figs. 9-11. Fig. 9 shows the unloaded state in which the spring members 216 are maintained at the mutual distance c by means of the biodegradable connection member 218. The distance c can be freely adapted to the specific application by choice of a suitable length of the members 218.

[0049] At their ends the biodegradable connecting members 218 are firmly fastened to the associated arm sections 222. Fig. 7 shows that the fastening point 232 is at a distance from the elbow sections 226. Fastening is performed at both ends of the biodegradable connecting member. The connection may also be made in other areas, such as a distance away from the end sections of the biodegradable connecting member.

[0050] Fig. 12 illustrates the Z-stent 210 of Fig. 6 in an expanded configuration within the range of thirty (30) days to one-hundred-eighty (180) days after the stent 210 has been expanded within the body and the connector members 218 have substantially biodegraded to leave the stent 210 with a plurality of substantially unconnected ring structures 214. As shown, the structure of the remainder of the stent 210 preferably retains its composition although, as discussed previously, the remainder of the stent may also biodegrade. At this point in time, the stent 210 is a modular, segmented stent 210 comprising multiple disconnected ring structures 214 which are preferably generally tubular and which allow the stent 210 to become flexible and conformable so as to substantially avoid mechanical irritation to the body's tissue. In other embodiments, the stent may retain a non-tubular shape, or a substantially integral tubular shape.

[0051] In yet another embodiment, as shown in Fig. 13, the present invention is utilized in a bifurcated stent device 310 with a Y-shaped structure which is used to treat an abdominal aorta aneurysm 340 (AAA device). Fig. 13 illustrates the AAA stent 310 in an expanded configuration shortly after deployment and prior to the biodegradable connector members 318 degrading. Such an AAA device is disclosed in PCT international publication number WO 98/53761 to William A. Cook which is hereby incorporated by reference. The stent 310 again comprises a plurality of cylindrical, ring structures 314, wherein each ring structure is comprised of one or more unit structures 322 formed of strut members 326 and bends 330 in a substantially zig-zagged pattern circumferentially around the stent. Fig. 14 illustrates the AAA stent 310 of Fig. 13 in an expanded configuration within the range of thirty (30) days to one-hundred-eighty (180) days after the stent 310 has been expanded within the body and the connector members 318 have substantially biodegraded to leave the stent 310 with substantially unconnected ring structures 314. As shown, the structure of the remainder of the stent 310 preferably retains its composition.

[0052] In practice, an expandable stent is provided having biodegradable connectors joining a plurality of cylindrical, serpentine ring structures in an unexpanded state. The stent may be self-expanding or balloon expandable. Any of the stent configurations previously discussed may be utilized, amongst others. The stent is delivered in its unexpanded state to a final destination within the body, such as stenosis or area of blockage within a vessel or artery. Generally, this is accomplished by advancing a catheter device through a patient's body in its unexpanded state by deploying a small guide wire and advancing the catheter device over the guide wire to its final destination. The stent is then expanded by inflating a balloon or releasing the self-expanding stent by methods known in the art to expand the stent radially so that the stent abuts against the walls of the artery. Preferably, within the range of thirty (30) days to one-hundred-eighty (180) days after the stent has been expanded within the body, the connector members substantially biodegrade to leave a stent with substantially disjointed ring structures. As discussed, other portions

of the stent structure may also substantially biodegrade to allow for a more flexible stent structure.

[0053] . Stents according to the present invention can be fabricated by any suitable process known in the art. The fabrication process need only be able to produce the ring architecture and biodegradable connector segments of the invention. The stents can be manufactured by having the stent pattern in a rod which would act as a mold. The ring structures of the stent may be set in this mold, and the biodegradable material used to form the connecting members could be injected into the mold to create the biodegradable connecting members. During manufacturing, anti-proliferate compounds may be incorporated into the biodegradable connecting members to inhibit cell proliferation.

[0054] Although the present invention has been described with reference to preferred embodiments, those skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention. As such, it is intended that the foregoing detailed description be regarded as illustrative rather than limiting and that the appended claims, including all equivalents thereof, are intended to define the scope of the invention.

CLAIMS

1. An expandable stent comprising:
a plurality of substantially cylindrical, serpentine ring structures, wherein each ring structure extends around a circumference of the stent and comprises at least one unit structure, wherein said at least one unit structure comprises a plurality of strut members and a plurality of bends, said strut members and bends forming a substantially zig-zag pattern; and
at least one connector member joining two of said ring structures when said stent is in an unexpanded state, wherein said at least one connector member is biodegradable and adapted to biodegrade when said stent is in an expanded state so that said two ring structures become substantially disjoined.
2. The expandable stent of claim 1; wherein said stent is a substantially integral, tubular shape in said unexpanded state.
3. The expandable stent of claim 1, wherein said stent is substantially Y-shaped when in said unexpanded state.
4. The expandable stent of claim 1, wherein said at least one connector member is made of one or more of polymers, copolymers, block polymers, poly-lactic acid, poly-glycolic acid, polyglycolides, polylactides, polycaprolactones, polyglycerol sebacate, polycarbonates, polyethylene oxide, polybutylene terephthalate, polydioxanones, hybrids, composites, collagen matrices with growth modulators, proteoglycans, glycosaminoglycans, vacuum formed small intestinal submucosa, fibers, chitin, and dextran.
5. The expandable stent of claim 1, wherein said at least one connector member is adapted to biodegrade within thirty days to one-hundred eighty days after said stent is expanded.

6. The expandable stent of claim 1, wherein said at least one connector member comprises a multitude of layers each having varying degradation rates.

7. The expandable stent of claim 1, wherein said at least one connector member comprises one layer having a substantially uniform degradation rate.

8. The expandable stent of claim 1, wherein said ring structures are made of one or more of nitinol, stainless steel, 316 L stainless steel, cobalt chromium, nickel titanium, platinum, and inconel.

9. The expandable stent of claim 1, wherein said ring structures comprise a non-biodegradable base material and one or more biodegradable coating layers.

10. The expandable stent of claim 9, wherein said one or more biodegradable coating layers is adapted to biodegrade within thirty days to one-hundred eighty days after said stent is expanded.

11. The expandable stent of claim 9, wherein said ring structures comprise multiple biodegradable coating layers having varying degradation rates.

12. The expandable stent of claim 9, wherein said ring structures comprise one biodegradable coating layer having a uniform degradation rate.

13. The expandable stent of claim 1, wherein said ring structures comprise a base material made of a combination of non-biodegradable materials and biodegradable polymers.

14. The expandable stent of claim 13, wherein said biodegradable polymers of said base material are adapted to biodegrade within thirty days to one-hundred eighty days after said stent is expanded.

15. The expandable stent of claim 13, wherein said biodegradable polymers of said base material have varying degradation rates and are dispersed unevenly throughout said base material.

16. The expandable stent of claim 13, wherein said biodegradable polymers of said base material are dispersed uniformly throughout said base material to provide a uniform degradation rate.

17. The expandable stent of claim 1, wherein said stent is one of self-expanding and balloon-expandable.

18. The expandable stent of claim 1, wherein when said at least one connector member biodegrades in an expanded state, said two ring structures become completely disjointed so that said stent does not form an integral structure.

19. The expandable stent of claim 1, wherein said at least one connector member is flexible prior to the stent being expanded.

20. The expandable stent of claim 1, wherein said at least one connector member is substantially U or V shaped.

21. The expandable stent of claim 1, wherein said at least one connector member is curved.

22. The expandable stent of claim 1, wherein said at least one connector member is straight.

23. The expandable stent of claim 1, wherein when said stent is in an unexpanded state said at least one connector member has first and second ends, said first end being connected to one of said plurality of bends of one of said two ring structures and said second end being connected to another of said plurality of bends of the other of said two ring structures.

24. The expandable stent of claim 1, wherein when said stent is in an unexpanded state there are two or more connector members joining said

two ring structures and adjacent connector members are circumferentially aligned.

25. The expandable stent of claim 1, wherein adjacent ring structures are axially aligned.

26. The expandable stent of claim 1, wherein a plurality of substantially straight tie-bars join a plurality of said ring structures.

27. A method of expanding a stent comprising:
providing an expandable stent which in an unexpanded state comprises a plurality of substantially cylindrical, serpentine ring structures, wherein each ring structure extends around a circumference of the stent, and at least one biodegradable connector member joining two of said ring structures;
delivering the stent in an unexpanded state to a final destination within a mammalian body;
expanding the stent; and
biodegrading said at least one connector member so that said two ring structures become substantially disjoined.

28. The method of claim 27 wherein, each ring structure extends around a circumference of the stent and comprises at least one unit structure, wherein said at least one unit structure comprises a plurality of strut members and a plurality of bends, said strut members and bends forming a substantially zig-zag pattern.

29. The method of claim 27, wherein said at least one connector member is made of one or more of polymers, copolymers, block polymers, poly-lactic acid, poly-glycolic acid, polyglycolides, polylactides, polycaprolactones, polyglycerol sebacate, polycarbonates, polyethylene oxide, polybutylene terephthalate, polydioxanones, hybrids, composites, collagen matrices with growth modulators, proteoglycans,

glycosaminoglycans, vacuum formed small intestinal submucosa, fibers, chitin, and dextran.

30. The method of claim 27, wherein said at least one connector member biodegrades within thirty days to one-hundred eighty days after said stent is expanded.

31. The method of claim 27, wherein said at least one connector member comprises a multitude of layers each having varying degradation rates.

32. The method of claim 27, wherein said at least one connector member comprises one layer having a substantially uniform degradation rate.

33. The method of claim 27, wherein said ring structures are made of one or more of nitinol, stainless steel, 316 L stainless steel, cobalt chromium, nickel titanium, platinum, and inconel.

34. The method of claim 27, wherein said ring structures comprise a non-biodegradable base material and one or more biodegradable coating layers.

35. The method of claim 34, containing the additional step of biodegrading said one or more biodegradable coating layers within thirty days to one-hundred eighty days after said stent is expanded.

36. The method of claim 34, wherein said ring structures comprise multiple biodegradable coating layers having varying degradation rates.

37. The method of claim 34, wherein said ring structures comprise one biodegradable coating layer having a uniform degradation rate.

38. The method of claim 27, wherein said ring structures comprise a base material made of a combination of non-biodegradable materials and biodegradable polymers.

39. The method of claim 38, containing the additional step of biodegrading said polymers of said base material within thirty days to one-hundred eighty days after said stent is expanded.

40. The method of claim 38, wherein said biodegradable polymers of said base material have varying degradation rates and are dispersed unevenly throughout said base material.

41. The method of claim 38, wherein said biodegradable polymers of said base material are dispersed uniformly throughout said base material to provide a uniform degradation rate.

42. The method of claim 27, wherein said stent is expanded using one of a self-expanding process and a balloon-expandable process.

43. The method of claim 27, wherein when said at least one connector member biodegrades in an expanded state, said two ring structures become completely disjoined so that said stent does not form an integral structure.

44. The method of claim 27, wherein said at least one connector member is flexible prior to the stent being expanded.

45. The method of claim 27, wherein said at least one connector member is one of substantially U and V shaped.

46. The method of claim 27, wherein said at least one connector member is curved.

47. The method of claim 27, wherein said at least one connector member is straight.

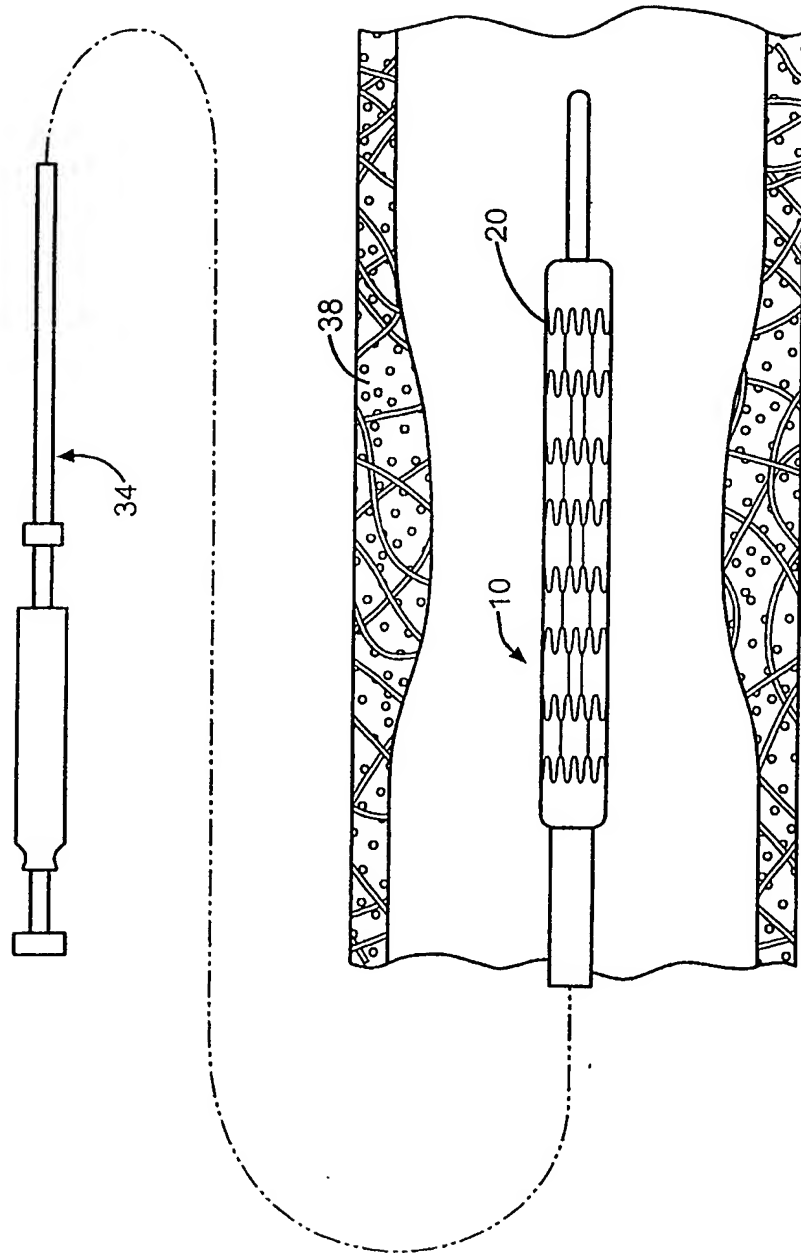


FIG. 1
(PRIOR ART)

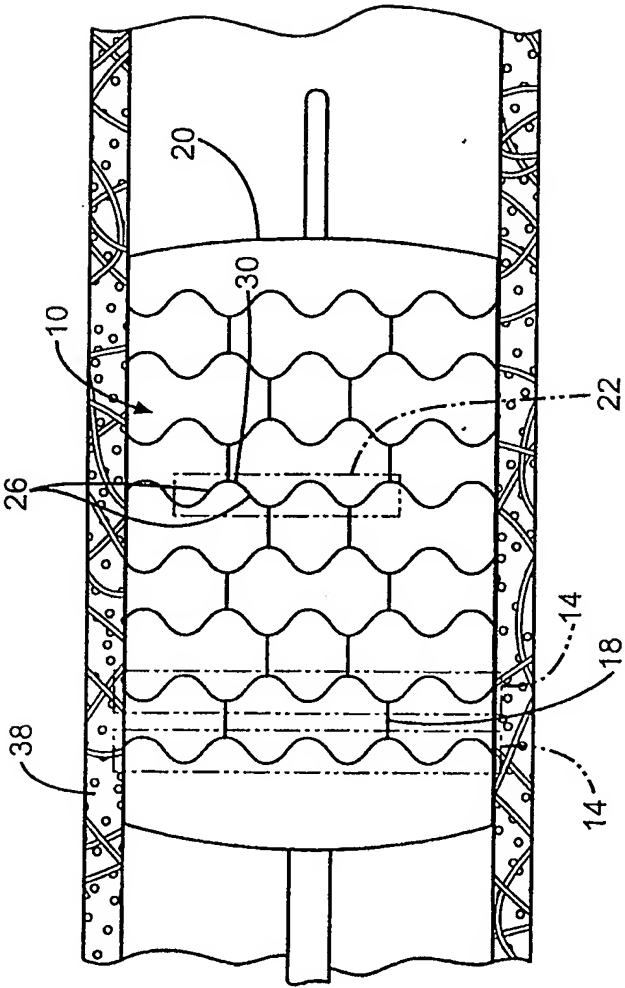
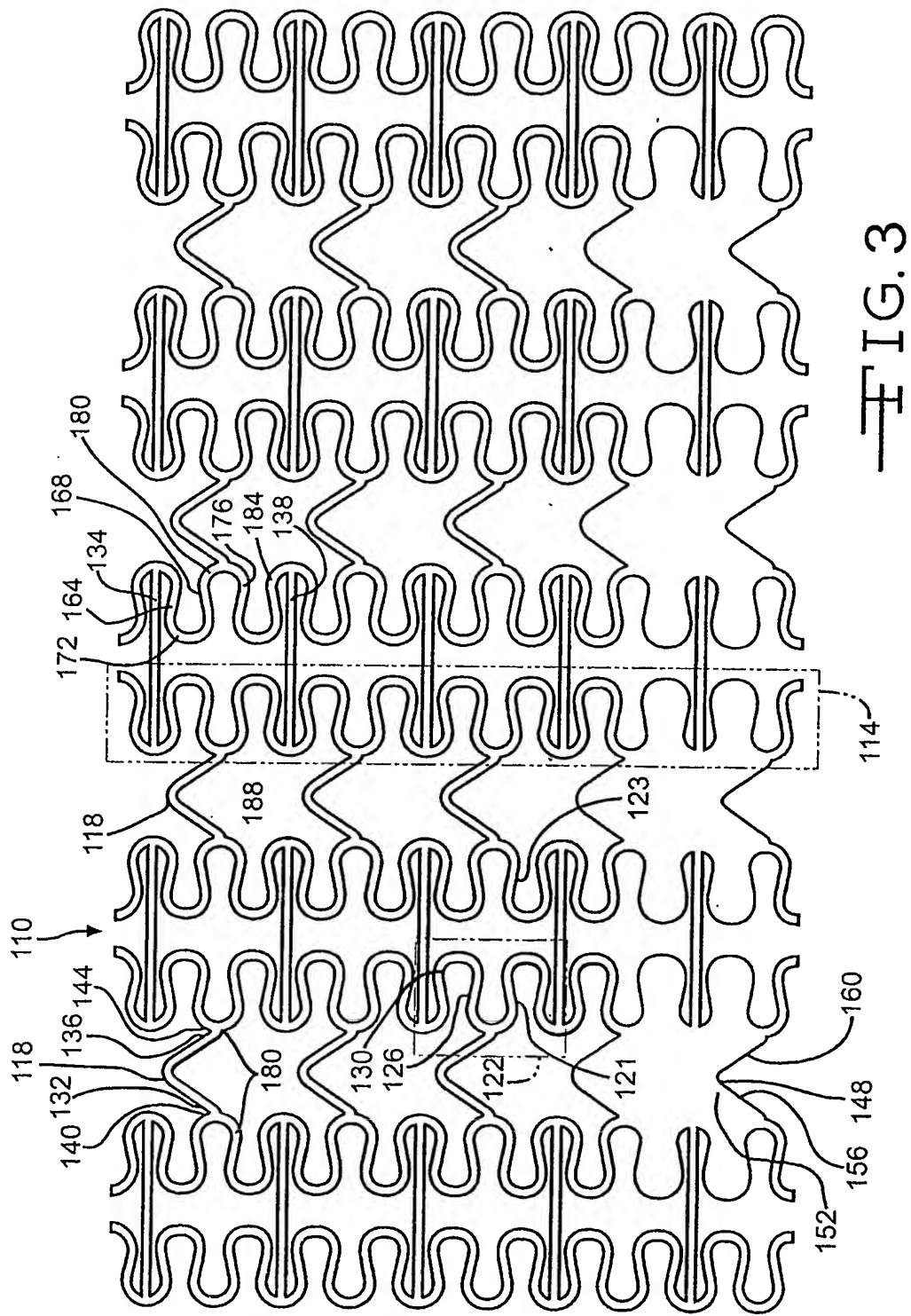


FIG. 2
(PRIOR ART)



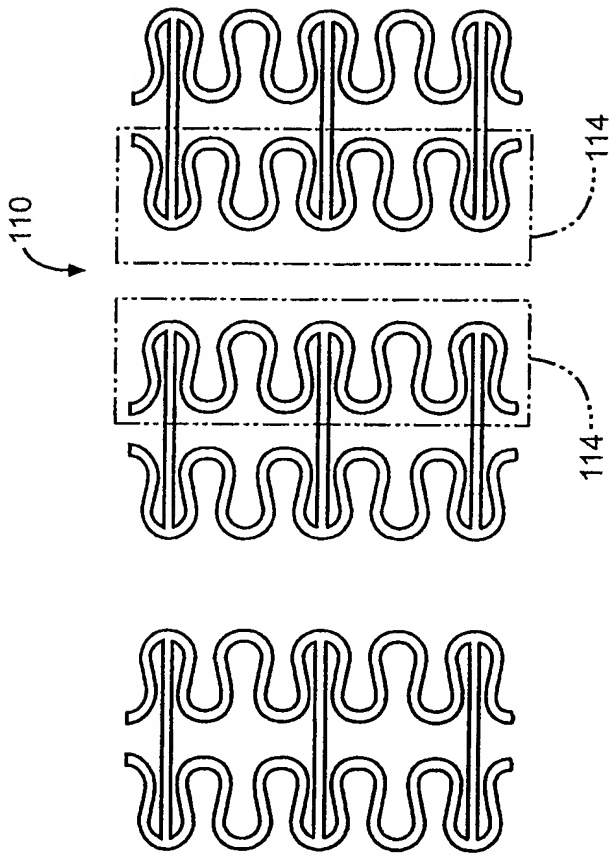


FIG. 4

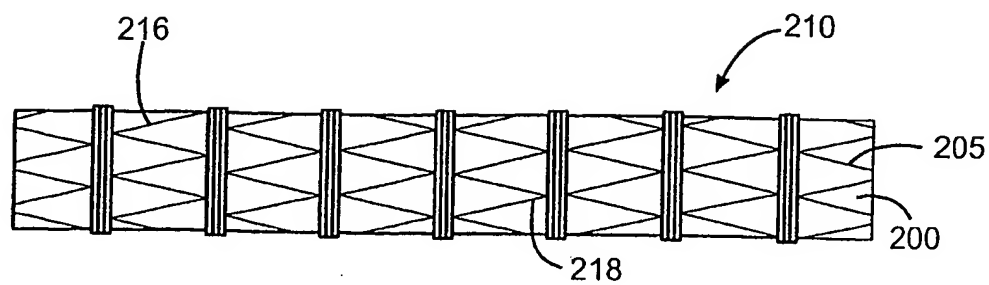


FIG. 5

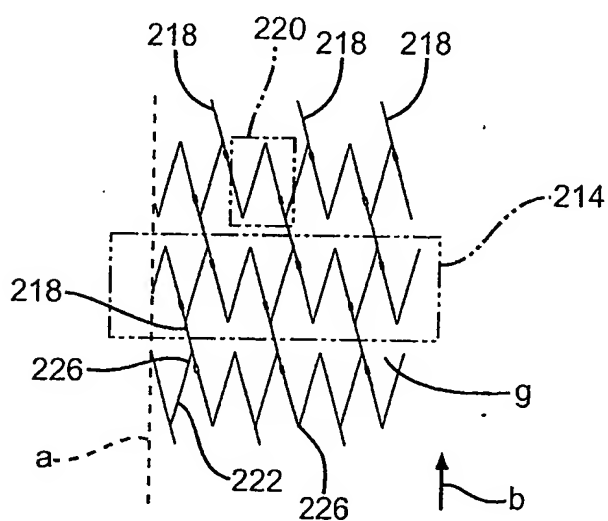


FIG. 6

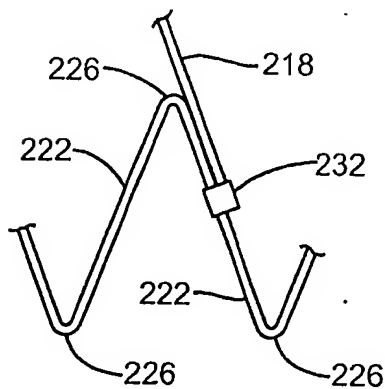


FIG. 7

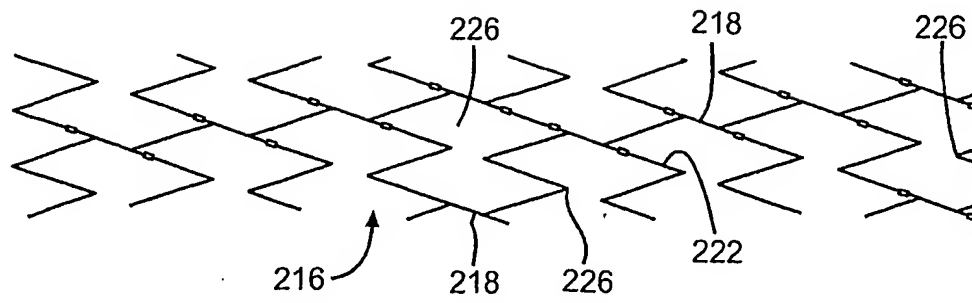


FIG. 8

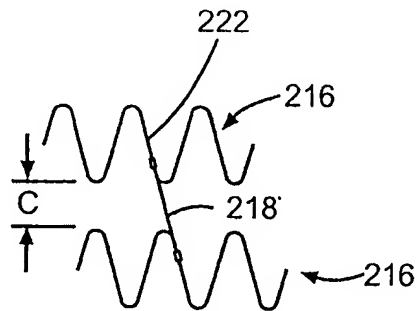


FIG. 9

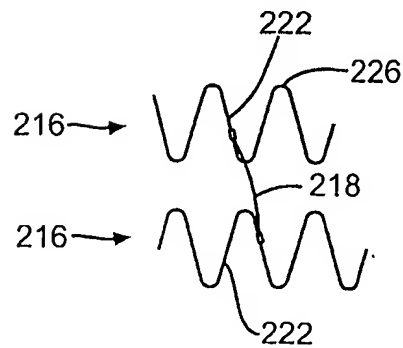


FIG. 10

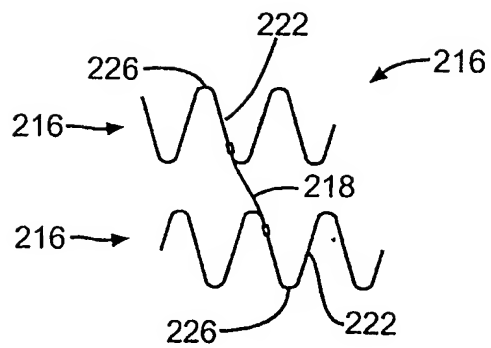


FIG. 11

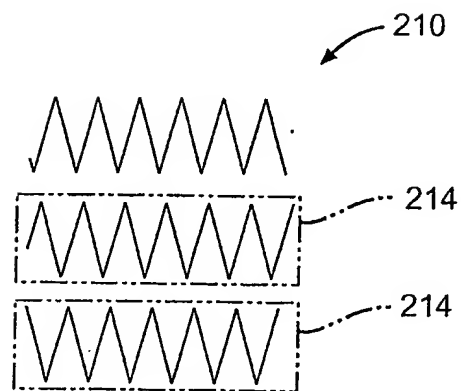


FIG. 12

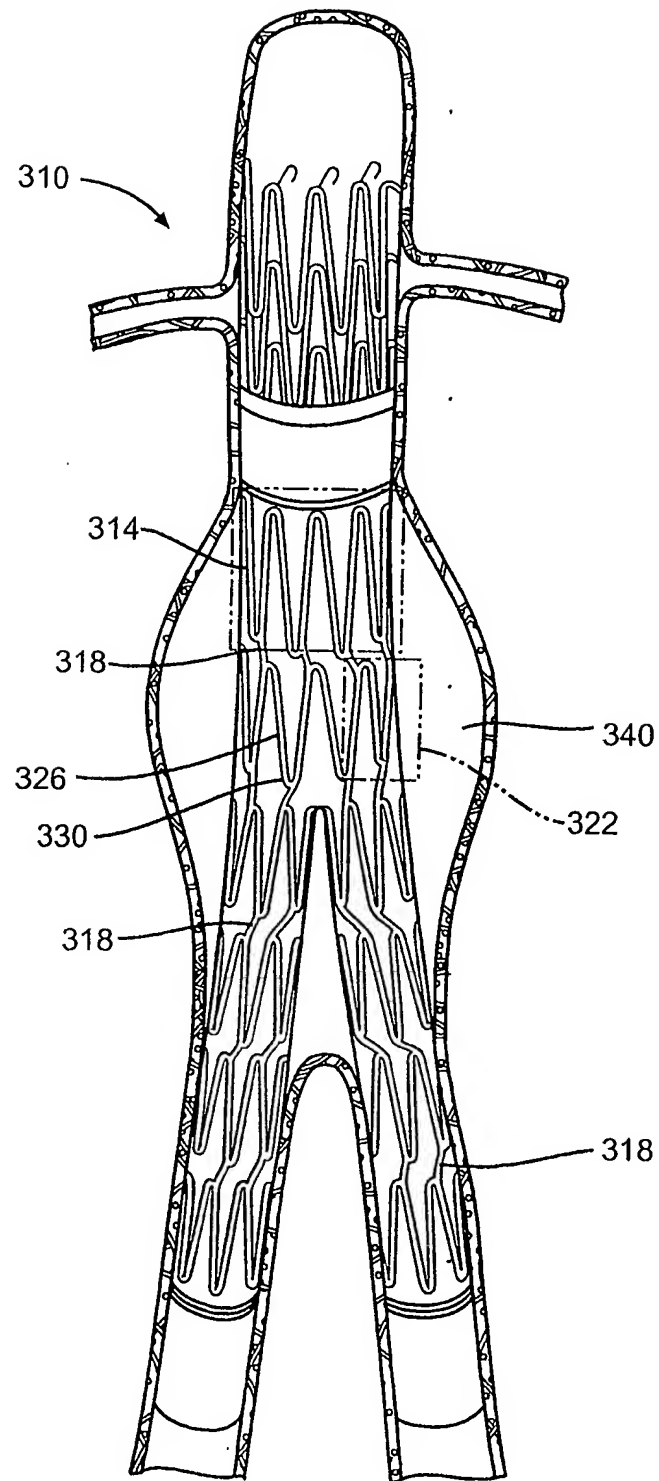


FIG. 13

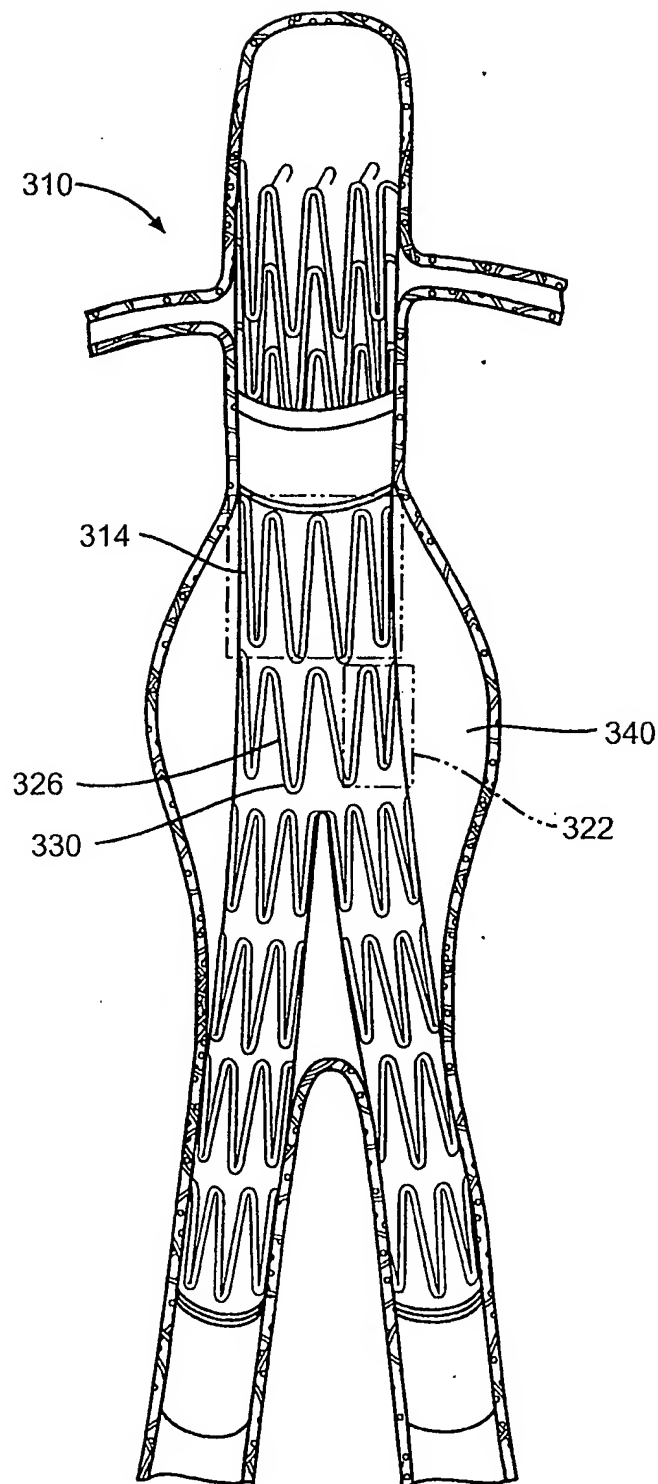


FIG. 14

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/005568

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/62708 A (MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH; CAMRUD, ALLAN, R;) 26 October 2000 (2000-10-26) page 1, line 15 - page 20, column 33; figures 1-31	1-26
X	US 2002/151964 A1 (SMITH SCOTT R ET AL) 17 October 2002 (2002-10-17) paragraph '0025! - paragraph '0039!; figures 1-6	1-26
P,X	WO 2004/045474 A (GMP CARDIAC CARE, INC) 3 June 2004 (2004-06-03) page 23, paragraph 2 - page 27, paragraph 1	1-26
	----- -/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the International filing date
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- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

20 June 2005

Date of mailing of the international search report

29/06/2005

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Authorized officer

Skorovs, P

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/005568

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, X	<p>WO 2004/052237 A (MEDTRONIC VASCULAR) 24 June 2004 (2004-06-24) paragraph '0003! - paragraph '0042!; figures 1-10</p> <p>-----</p>	1-26

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2005/005568

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 27-47
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2005/005568

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 0062708	A	26-10-2000	US 6258117 B1	10-07-2001
			AU 772971 B2	13-05-2004
			AU 4241000 A	02-11-2000
			CA 2370184 A1	26-10-2000
			EP 1173109 A1	23-01-2002
			JP 2002541909 T	10-12-2002
			WO 0062708 A1	26-10-2000
			US 2003078649 A1	24-04-2003
			US 6485510 B1	26-11-2002
			US 2004167616 A1	26-08-2004
US 2002151964	A1	17-10-2002	US 6409754 B1	25-06-2002
			AT 277568 T	15-10-2004
			CA 2373780 A1	11-01-2001
			DE 60014373 D1	04-11-2004
			DE 60014373 T2	24-02-2005
			DK 1191904 T3	07-02-2005
			EP 1191904 A1	03-04-2002
			EP 1477130 A2	17-11-2004
			JP 2003503152 T	28-01-2003
			WO 0101888 A1	11-01-2001
WO 2004045474	A	03-06-2004	AU 2003290881 A1	15-06-2004
			WO 2004045474 A1	03-06-2004
			US 2004106975 A1	03-06-2004
WO 2004052237	A	24-06-2004	AU 2003297832 A1	30-06-2004
			WO 2004052237 A2	24-06-2004
			US 2004172127 A1	02-09-2004